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EXAMINER	
FUELLING, MICHAEL	

ART UNIT	PAPER NUMBER
3626	

NOTIFICATION DATE	DELIVERY MODE
07/21/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/589,560	Applicant(s) ABRAHAM-FUCHS ET AL.	
	Examiner Michael Fuelling	Art Unit 3626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 March 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☒ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

This is a non-final Office Action for Application Number 10/589,560 filed August 16, 2006.

Claims 1-23 have been amended and examined.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on March 18, 2010 has been entered.

Priority

Acknowledgment is made of applicant's claim for foreign priority based on applications filed in Germany on 2/18/2004 and 10/28/2004. It is noted, however, that applicant has not filed certified copies of the 10 2004 008 194.8 and 10 2004 052 473.4 German applications as required by 35 U.S.C. 119(b).

Drawings

The drawings have been accepted as noted in the previous action.

Response to Amendment

The 35 USC 101 and 102(b) claim rejections are withdrawn, however, applicant's amendments are insufficient to place this case in a condition for allowance.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

1. Claims 1-6, 11-14 and 17-23 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 1 was amended to recite an “access control” and such component is not described in the written description. Claims 2-6, 11-14 and 21-23 have the same defect.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1-6, 11-14 and 17-23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A. Claim 1 recites “is one of a portable memory device transported by the patient and part of a * * *”. This recitation is vague and indefinite because the “one of” recitation does not appear to correspond with more than one possible limitation. Claims 2-6, 11-14 and 21-23 do

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not cure the defect. It could be interpreted applicant meant “a part of a” (emphasis added), however, to further compact prosecution, it will be interpreted the “one of” recitation is superfluous, and applicant intended the claimed invention to include both limitations.

B. Referring to claims 17-20, claim elements “memory means”, “input means” and “reading means” are means (or step) plus function limitation that invokes 35 U.S.C. 112, sixth paragraph. However, the written description fails to disclose the corresponding structure, material, or acts for the claimed function.

Applicant is required to:

(a) Amend the claim so that the claim limitation will no longer be a means (or step) plus function limitation under 35 U.S.C. 112, sixth paragraph; or

(b) Amend the written description of the specification such that it expressly recites what structure, material, or acts perform the claimed function without introducing any new matter (35 U.S.C. 132(a)).

If applicant is of the opinion that the written description of the specification already implicitly or inherently discloses the corresponding structure, material, or acts so that one of ordinary skill in the art would recognize what structure, material, or acts perform the claimed function, applicant is required to clarify the record by either:

(a) Amending the written description of the specification such that it expressly recites the corresponding structure, material, or acts for performing the claimed function and clearly links or associates the structure, material, or acts to the claimed function, without introducing any new matter (35 U.S.C. 132(a)); or

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(b) Stating on the record what the corresponding structure, material, or acts, which are implicitly or inherently set forth in the written description of the specification, perform the claimed function. For more information, see 37 CFR 1.75(d) and MPEP §§ 608.01(o) and 2181.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claim 1-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brimm et al., US Patent Number 5,072,383 (Brimm) in view of Dempsey et al., US Patent No. 5,417,222 (Dempsey)

Referring to claims 1, 7 and 17, Brimm discloses a method and system, including a computer memory (C4, L24), the method comprising:

- *storing data associated with a protocol of a medical regimen* (C4, L10-20 "automated clinical records management")
- *storing patient-related data associated with the patient and the medical regimen* (Abstract patient information system)
- *reading by a computer associated with another doctor assigned to the patient the data* (Abstract physician and C4, L25 terminal unit with display means)

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While Brimm does not appear to expressly use the term “clinical study”, Brimm discloses a medical regimen, as detailed above, and a clinical study is a medical regimen. Further, applicant’s use of the term “clinical study” merely is a nonfunctional description of the data. Nonfunctional descriptive material cannot render nonobvious in an invention that would have otherwise been obvious. *In re Ngai*, 367 F.3d 1336, 1339 (Fed. Cir. 2004). *Cf. In re Gulack*, 703 F.2d 1381, 1385 (Fed. Cir. 1983) (when descriptive material is not functionally related to the substrate, the descriptive material will not distinguish the invention from the prior art in terms of patentability).

Brimm does not appear to expressly disclose a portable device transported by the patient, which is a part of a network, where such device could be controlled by the patient. Dempsey discloses such a device (Abstract and Fig. 1). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the invention of Brimm to include the device of Dempsey and the results would have been predictable.

Referring to claim 2, Brimm and Dempsey disclose all of the limitations of claim 1 and Brimm further discloses: *data is stored in the memory by a study doctor* (C9, L17 physician enters orders).

Referring to claim 3, Brimm and Dempsey disclose all of the limitations of claim 1 and Brimm further discloses: *another doctor reads the data out from the memory before an interaction with the patient* (C5, L53).

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Referring to claim 4, Brimm and Dempsey disclose all of the limitations of claim 1 and Brimm further discloses: *data is stored in the memory with standardized structuring* (Fig. 10).

Referring to claim 5, Brimm and Dempsey disclose all of the limitations of claim 1 and Brimm further discloses: *clear instructions to another doctor are stored as data* (C11, L25 creation of task list).

Referring to claim 6, Brimm and Dempsey disclose all of the limitations of claim 1 and Brimm further discloses: *data is assigned to various classes, and another doctor reads only information of one class out from the memory* (C9, L19 select from a list the type of information).

Referring to claim 8, Brimm and Dempsey disclose all of the limitations of claim 7 and Brimm further discloses: *the memory is portable* (C6, L52 discs).

Referring to claim 9, Brimm and Dempsey disclose all of the limitations of claim 7 and Brimm further discloses: *the memory is part of a data network* (C5, L64 network), *to which data input and output devices are connectable* (C6, L18 monitoring equipment) *and wherein authorization, is required for access to the data* (C9, L13 entry to the system restricted by security measures).

Referring to claim 10, Brimm and Dempsey disclose all of the limitations of claim 7 and Brimm further discloses: *the data reading device is portable* (**11** bedside workstation).

Referring to claim 11, Brimm and Dempsey disclose all of the limitations of claim 2 and Brimm further discloses: *another doctor reads the data out from the memory before an interaction with the patient* (see claim 3 details above).

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Referring to claim 12, Brimm and Dempsey disclose all of the limitations of claim 2 and Brimm further discloses: *the data are stored in the memory with standardized structuring* (see claim 4 details above).

Referring to claim 13, Brimm and Dempsey disclose all of the limitations of claim 2 and Brimm further discloses: *clear instructions to another doctor are stored as data* (see claim 5 details above).

Referring to claim 14, Brimm and Dempsey disclose all of the limitations of claim 2 and Brimm further discloses: *the data are assigned to various classes, and another doctor reads only information of one class out from the memory* (see claim 6 details above).

Referring to claim 15, Brimm and Dempsey disclose all of the limitations of claim 8 as detailed above and Brimm further discloses: *the data reading device is portable* (C6, L19 such as a respiratory monitor; **8 10** bedside devices).

Referring to claim 16, Brimm and Dempsey disclose all of the limitations of claim 9 as detailed above and Brimm further discloses: *the data reading device is portable* (C6, L19 such as a respiratory monitor; **8 10** bedside devices).

Referring to claim 18, Brimm and Dempsey disclose all of the limitations of claim 17 as detailed above and Brimm further discloses: *the memory means is portable* 9 (C6, L52 discs).

Referring to claim 19, Brimm and Dempsey disclose all of the limitations of claim 17 as detailed above and Brimm further discloses: *the memory means is part of a data network* (C5, L64 network), *to which data input and output devices are connectable* (C6,

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L18 monitoring equipment) *and wherein authorization is required for access to the data* (C9, L13 entry to the system restricted by security measures).

Referring to claim 20, Brimm and Dempsey disclose all of the limitations of claim 17 as detailed above and Brimm further discloses: *the reading means is portable* (C6, L19 such as a respiratory monitor; **8 10** bedside devices).

Referring to claim 21, Brimm and Dempsey disclose all of the limitations of claim 1 and Brimm further discloses: *another doctor is a doctor who is at least one of not associated to the clinical study and external to the clinical study* (Abstract physician).

Referring to claim 22, Brimm and Dempsey disclose all of the limitations of claim 1 and Brimm further discloses: *the clinical study is conducted to test at least one of medicaments, methods of surgical intervention, therapies, and diagnostic devices* (C6, L19 such as a respiratory monitor; **8 10** bedside devices).

Referring to claim 23, Brimm and Dempsey disclose all of the limitations of claim 1 and Brimm further discloses: *displaying, by the computer, at least one of the study-related and the patient- related data to another doctor device* (C4, L25 terminal unit with display means).

Response to Arguments

Applicant's arguments received March 18, 2009 have been fully considered, but they are not persuasive, and are further moot in view of the new grounds of rejection.

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Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Fuelling whose telephone number is (571)270-1367. The examiner can normally be reached on Monday - Friday, 8:30 am - 5 pm, EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Morgan can be reached on (571)272-6773. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/M.F./

Examiner, Art Unit 3626

/C. Luke Gilligan/

Primary Examiner, Art Unit 3626